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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/630,454	LIAW ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 08 December 2003.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) 1-5,10 and 17-23 is/are withdrawn from consideration.

5)☒ Claim(s) 9 is/are allowed.

6)☒ Claim(s) 6-8 and 11 is/are rejected.

7)☒ Claim(s) 12-16 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 12/08/03 in response to the non-final Office Action mailed 09/24/03.

Status of Claims

2) Claims 6, 8, 9 and 11 have been amended via the amendment filed 12/08/03.

Claims 1-23 are pending.

Claims 6-9 and 11-16 are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

5) The objection to claims 9 and 11 made in paragraph 14 of the Office Action mailed 05/30/03 is withdrawn in light of Applicants' amendments to the claims.

Rejection(s) Withdrawn

6) The rejection of claim 6 made in paragraph 11(a) of the Office Action mailed 05/30/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

7) The rejection of claim 6 made in paragraph 11(b) of the Office Action mailed 05/30/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

8) The rejection of claim 11 made in paragraph 11(c) of the Office Action mailed 05/30/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

9) The rejection of claim 6 made in paragraph 11(d) of the Office Action mailed 05/30/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

10) The rejection of claim 8 made in paragraph 11(e) of the Office Action mailed 05/30/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

11) The rejection of claim 11 made in paragraph 11(f) of the Office Action mailed 05/30/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

12) The rejection of claims 7 and 8 made in paragraph 11(g) of the Office Action mailed 05/30/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

13) The rejection of claims 11-16 made in paragraph 12 of the Office Action mailed 05/30/03 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendments to the claims and/or the base claim(s).

14) The rejection of claims 11-16 made in paragraph 13 of the Office Action mailed 05/30/03 under 35 U.S.C. § 112, first paragraph, as containing inadequate written description, is withdrawn in light of Applicants' amendments to the claims and/or the base claim(s).

15) The rejection of claims 6-8 made in paragraph 22 of the Office Action mailed 06/04/03 (paper no. 12) and maintained in paragraph 10 of the Office Action mailed 09/24/03 under 35 U.S.C. § 102(b) as being anticipated by Shijo *et al.* (US 5,077,207), is withdrawn in light of Applicants' amendments to the claims and/or the base claim. A modified rejection is made below to meet the claims, as amended.

Response to Applicants' Arguments on Shijo *et al.*

16) Applicants contend that the culture medium of Shijo *et al.* was autoclaved '*before*' the bacteria were added, and that the wastestream media defined by the term 'raffinate' as claimed is not the same as the culture medium of Shijo *et al.* in that the heat sterilization would have to occur *after* culturing the bacteria and an ion chromatography step [Emphasis in original]. Applicants then state that amendment to claim 6 clarifies that the raffinate is heat sterilized and the bacterial strain B is isolated from said heat sterilized raffinate-containing medium. Applicants state that the definition of 'raffinate' in the specification on page 7, lines 3-8, "limits" the claims to a wastestream product from an ion exchange operation for lysine recovery. Applicants argue that *In re Van Geuns* does not apply as the definition of the present specification is merely defining a limitation already in the claim. Applicants cite *In re Zletz* (893 F.2d 319, Fed. Cir., 1989) and state that the meaning of the claim has been clearly stated as being 'limited' to the definition disclosed in the specification and therefore, the claims should be examined 'with that meaning' as stated by the court. Applicants then point to page 9, line 29 and bridging over to page 10, line 3 and page 10 of the specification and state that these parts of the specification provided 'further' definitions of the term. See pages 13 and 14

of Applicants' amendment filed 12/08/03. With regard to the product-by-process aspect of the rejection, Applicants state that it does not apply in the present application, as the claimed process would produce a materially distinct product, a raffinate-resistant bacterial strain, than is taught by Shijo *et al.* Applicants contend that the growth inhibitory substances contained in heat sterilized raffinate would not be present in the non-raffinate-containing medium of Shijo *et al.* Applicants submit that the claimed microorganisms have been selected to grow in the raffinate medium that contains the inhibitory substances and that the microorganisms would not have the superior growth characteristics as the claimed microorganisms.

Applicants' arguments have been carefully considered, but are non-persuasive. Contrary to Applicants' assertion, the meaning of 'raffinate' as described within the instant specification is not limited to 'a wastestream product from an ion exchange operation for lysine recovery'. The multiple non-limiting definitions or descriptions for the limitation 'raffinate' as provided within the instant application are reproduced herebelow:

I. Raffinate refers to a wastestream product from an ion-exchange operation for lysine recovery. See lines 3 and 4 on page 7 and line 1 on page 8 of the specification.

II. Raffinate contains a large amount of ammonia sulfate, L-lysine, other amino acids, salts, and carbohydrates. See lines 4-6 on page 7 and lines 2 and 3 on page 8 of the specification.

III. The term "raffinate" is most closely associated with the chemical engineering field in the area of liquid-liquid extraction. The term is defined in solvent refining as "that portion of the treated liquid mixture that remains undissolved and is not removed by the selective solvent" (*Dictionary of Scientific and Technical Terms*, Sybil P. Parker, ed., McGraw-Hill, 1989). See the last sentence on page 9 and the sentence bridging pages 9 and 10.

IV. The term raffinate as used in connection with ion-exchange chromatography refers to that portion of the liquid mixture that is not selectively bound by the chromatographic resin. See lines 6-8 on page 10 of the specification.

V. In connection with the fermentative production of amino acids, the raffinate is that portion of the cell culture media that does not bind to the chromatographic column; raffinate is the broth effluent waste stream product generated during the ion-exchange chromatographic purification of an amino acid. See lines 8-12 on page 10 of the specification.

VI. Raffinate refers to the first waste stream product generated after the initial application of the growth media to the ion-exchange resin. See lines 12-14 of page 10 of the specification.

In addition to these descriptions, via page 13 and 14 of their amendment filed 12/08/03, Applicants provide an additional definition for the term 'raffinate' as recognized in the art:

VII. The definition of the term 'raffinate' is known in the art to be 'a phrase remaining after

extraction of some specified solute(s). When necessary, it should be further specified, e.g. scrub raffinate..... The term should normally be applied only to waste streams ...'. See third full paragraph on page 13 of Applicants' amendment filed 12/08/03.

The above-cited multiple definitions for the term 'raffinate' within the instant specification clearly represent non-limiting definitions, and are inconsistent with Applicants' statement on page 12 of the specification that 'the definition of the "raffinate" in the specification on page 7, lines 3-8, *limits* the claims to a wastestream product from an ion exchange operation for lysine recovery [Emphasis added]. Applicants in fact acknowledge on page 13 of their amendment filed 12/08/03 that the specification, as filed, provided 'further' definitions of the term 'raffinate'. Given these multiple descriptions within the specification for the term 'raffinate' and given the lack of incorporation of the alleged 'limiting' definition into the claim(s), the Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. MPEP 2111 [R-1] states that during patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification'. *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Limitations appearing in the specification but not recited in the claim, i.e., wastestream product from an ion exchange operation for lysine recovery, are not read into the claim. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ('During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow ... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process'. In the instant application, consistent with *In re Zletz*, the term 'raffinate' has been interpreted as broadly as the description(s) in the disclosure allows. In light of the multiple non-limiting descriptions for the term 'raffinate' within the specification, the applied prior art only has to meet any one of such descriptions. The disclosure of Shijo *et al.* meets the description and anticipates the claims. See the art rejection below. In the absence of the alleged limiting description in the claims, whether or not Shijo's culture medium is autoclaved before or after culturing the bacteria and an ion chromatography step is irrelevant. The fact that Shijo's mutant strain grew in the autoclaved raffinate-containing culture medium and showed overproduction of threonine is *prima facie* evidence that the mutant strain was not inhibited by any inhibitory substances and that it did show superior growth characteristics. See the art rejection below.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections

are necessitated by Applicants' amendments.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

17) Claims 6-8 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 6, as amended, includes the limitation: 'heat sterilized' raffinate. Applicants do not point to a specific part of the specification that provides descriptive support for a bacterial culture medium containing at least 1% 'heat sterilized raffinate'. A review of the specification indicates that while there is descriptive support for '[h]eat sterilized raffinate-containing medium' (see line 9 on page 7), there appears to be no support for a bacterial culture medium containing "heat sterilized raffinate", as recited currently. A '[h]eat sterilized raffinate-containing medium' is not the same in scope as 'a bacterial culture medium containing ..... 1% heat sterilized raffinate based on ammonia sulfate content' (see lines 4 and 5 of claim 6, for example). The latter encompasses a non-heat sterilized culture medium containing separately heat-sterilized raffinate. The latter does not appear to have support in the specification as originally filed. Therefore, the new limitations in the instant claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P. 608.04 to 608.04(c).

Applicants are invited to point to specific line and page numbers of the specification, as originally filed, that provide descriptive support for the limitations identified above, or to remove the new matter from the claim(s).

18) Claims 6-8 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 11, as amended, includes the limitation: 'a mutant of (a), (b), (c), (d) or (e), wherein said mutant has increased L-lysine amino acid production when compared to the L-lysine producing *Corynebacterium* strain before being mutagenized'. Applicants do not point to a specific part of the specification that provides descriptive support for a bacterial culture medium containing at least 1% 'heat sterilized raffinate'. A review of the specification indicates that while there is descriptive support on page 8, lines 14 and 15 and Table 4 for L-lysine producing mutant *Corynebacterium* strains, NRRL B-30059 (L63.148); NRRL B-30060 (L64.132); NRRL B-30061 (L69.53); NRRL B-30062 (L69.74); and NRRL B-

30063 (L69.100), which are obtained by mutagenizing a parental *Corynebacterium* strain 108T125, LS8.23 or 96T116. However, there is no descriptive support for a mutant of the mutant NRRL B-30059 (L63.148); NRRL B-30060 (L64.132); NRRL B-30061 (L69.53); NRRL B-30062 (L69.74); and NRRL B-30063 (L69.100) *Corynebacterium* strain, which mutant of the mutant 'has increased L-lysine amino acid production when compared to the L-lysine producing *Corynebacterium* strain before being mutagenized', as recited currently. Applicants are not in possession of the mutant of a mutant claimed in claim 11(f). Therefore, the new limitations in the instant claim are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P. 608.04 to 608.04(c).

Applicants are invited to point to specific line and page numbers of the specification, as originally filed, that provide descriptive support for the limitations identified above, or to remove the new matter from the claim(s).

19) Claim 11 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated raffinate-resistant, mutant *Corynebacterium* strains, NRRL B-30059 (L63.148); NRRL B-30060 (L64.132); NRRL B-30061 (L69.53); NRRL B-30062 (L69.74); and NRRL B-30063 (L69.100), wherein said mutant strains show an increased production of L-lysine compared to the parental wild L-lysine-producing *Corynebacterium* strain, 108T125, LS8.23 and 96T116, does not reasonably provide enablement for a mutant of NRRL B-30059 (L63.148); NRRL B-30060 (L64.132); NRRL B-30061 (L69.53); NRRL B-30062 (L69.74); and NRRL B-30063 (L69.100) strains of *Corynebacterium,* which mutant of the above-mentioned mutant has increased L-lysine amino acid production when compared to the L-lysine-producing *Corynebacterium* strain before being mutagenized, i.e., *Corynebacterium* strain, 108T125, LS8.23 or 96T116, as claimed currently.

The instant claims are evaluated based on the *Wands* analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- The quantity of experimentation necessary (time and expense);
- The amount of direction or guidance presented;
- The presence or absence of working examples of the invention;
- The nature of the invention;
- The state of the art;
- The relative skill of those in the art;
- The predictability or unpredictability of the art; and
- The breadth of the claims.

The instant claim 11 part (f) is directed to a mutant of a mutant *Corynebacterium* strain recited in

parts (a) through (e) of the claim. The *Corynebacterium* strains recited in claim 11, parts (a) through (e) are themselves mutants of the parental *Corynebacterium* strain, i.e., 8T125, strains LS8.23 and 96T116. The mutant recited in part (f) of claim 11 is a further mutant of NRRL B-30059 (L63.148); NRRL B-30060 (L64.132); NRRL B-30061 (L69.53); NRRL B-30062 (L69.74); or NRRL B-30063 (L69.100) mutant. The mutant recited in part (f) of claim 11, as amended, is required to have 'increased L-lysine amino acid production when compared to the L-lysine producing *Corynebacterium* strain before being mutagenized', i.e., the non-mutagenized wild (grand)parent strain recited in line 1 of the claim. A review of the specification indicates that the mutant *Corynebacterium* strains recited in parts (a) through (e) of the claim are enabled as improved raffinate-resistant mutants producing increased L-lysine when compared to the non-mutagenized wild parental *Corynebacterium* strains 8T125, strains LS8.23 and 96T116 when gown in a culture medium containing at least 1% raffinate. See Examples 1-4 and Tables 2-4. However, there is no showing that a further mutant of mutants NRRL B-30059 (L63.148); NRRL B-30060 (L64.132); NRRL B-30061 (L69.53); NRRL B-30062 (L69.74); and NRRL B-30063 (L69.100) are produced, which showed increased L-lysine production compared to the non-mutagenized grant parental strain, 8T125, strains LS8.23 and 96T116. The specification lacks data similar to those shown in Tables 2-4 for the mutant claimed in claim 11(f) showing that the second mutant of one of the mutants recited in claims 11(a)-(e) does show an increased L-lysine production when compared to its non-mutagenized wild grandparental strain, 8T125, strains LS8.23 or 96T116. There is no guidance or teaching within the instant specification as to how to produce a second mutant of the mutant of *Corynebacterium* strain, NRRL B-30059 (L63.148); NRRL B-30060 (L64.132); NRRL B-30061 (L69.53); NRRL B-30062 (L69.74); or NRRL B-30063 (L69.100), such that the second mutant of claim 11(f) produces increased L-lysine when compared to the non-mutagenized L-lysine-producing wild grandparental strain, 8T125, strains LS8.23 or 96T116. The specification does not teach how to create a further mutant of an increased L-lysine-producing mutant *Corynebacterium* strain, NRRL B-30059 (L63.148); NRRL B-30060 (L64.132); NRRL B-30061 (L69.53); NRRL B-30062 (L69.74); or NRRL B-30063 (L69.100), such that the mutant of the mutant retains the ability to show increased L-lysine production compared to the non-mutagenized wild grandparent *Corynebacterium* strain. The art of bacterial mutation is very unpredictable. Given that predictability or unpredictability is one of the *Wands* factors, this is a critical issue because, even if one of skill in the art is able to further mutate an already mutated *Corynebacterium* strain, the effects of a second mutation, in an already mutated strain, on the ability to show increased lysine production are not predictable. The breadth of the claims is clearly not commensurate with the scope of the evidence or the enabling disclosure. The ability to reproducibly practice the full scope of the claimed invention is well outside the realm of routine experimentation. In view of the lack of enabling disclosure, the lack of specific guidance and direction to practice the full scope of the

claimed invention, the mutational unpredictability, the quantity of experimentation necessary, and the breadth of the claims, undue experimentation would have been required at the time of the effective filing date of the instant application for one of skill in the art to reproducibly practice the full scope of the claimed invention. The enablement (scope) provisions of 35 U.S.C. § 112, first paragraph, are not met.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

20) Claims 6-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 6, as amended, is confusing in the recitation 'bacterial culture medium containing at least about 1% heat sterilized raffinate' (see part b of the claim). It is unclear how this bacterial culture medium differs from the 'raffinate medium which has been heat-sterilized' recited in part (c) of the claim. Is the 'raffinate medium' recited in part (c) a bacterial culture medium similar to the one recited in part (b)? Does it contain at least 1% raffinate, or any amount of raffinate?

(b) Claims 7 and 8, which depend directly or indirectly, from claim 6, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

21) Claims 6-8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Shijo *et al.* (US 5,077,207, already of record).

The term 'raffinate' is interpreted in this rejection as containing a large amount of ammonia sulfate, amino acids, various salts, and carbohydrates. The amended phrase in claim 6: 'in a bacterial culture medium containing ..... heat sterilized raffinate based on ammonia sulfate content', is interpreted in this rejection as encompassing a raffinate-containing bacterial culture medium that has been heat-sterilized.

Shijo *et al.* disclosed a mutant bacterial strain, for example, a mutant *Brevibacterium* sps. (i.e., strain B). The parent strain (i.e., strain A) was subject to mutagenesis by treatment with a mutagen, such as, NG; it was cultured in an autoclaved (i.e., heat-sterilized) culture medium containing 70 g/l of ammonium sulfate; 30 ml/l of soybean hydrolysate; glucose; KH_2PO_4; $MgSO_4.7H_20$; $FeSO_4.7H_20$; thiamine hydrochloride and biotin; and the mutant strain exhibiting maximum production of threonine (i.e., an amino acid) was selected, which produced increased amounts of threonine compared to the parent strain (see Examples 1 and 2; Table 3; column 2; and last paragraph in column 4). That the prior art culture medium contained the recited raffinate that was heat-sterilized in the autoclaved culture medium is inherent from the teachings of Shijo *et al.* in light of the fact that it included a large amount of ammonia sulfate, an amino acid such as L-histidine, various salts, a carbohydrate such as glucose, and other amino acids and/or carbohydrates intrinsically present in soybean hydrolysate. The fact that the mutant strain grew in such a heat-sterilized culture medium and exhibited the overproduction of threonine suggests that it was raffinate-resistant and that its' growth was

not inhibited by any inhibitory substances.

It is further noted that the instant claims are product-by-process claims, which are not limited to the manipulations of the recited steps, but only the structure implied by the steps. MPEP § 2113 states:

> [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)* (citations omitted).

A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. Applicants have not shown that the alleged difference(s) in the process results in a product that is structurally different from the product of the prior art. In the instant case, Applicants have not shown that the underlying structure of the prior art bacterial strain differs from that of the instantly claimed bacterial strain. The prior art product meets the instant claims and anticipates the claimed product.

Claims 6-8 are anticipated by Shijo *et al.*

Remarks

22) Claims 6-8 and 11 stand rejected. Claim 9 is allowable. Claims 12-16 are objected to as being dependent from a rejected base claim.

23) Applicants' amendments necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

24) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments

is (703) 872-9307.

25) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March, 2004

S. DEVI, PH.D.
PRIMARY EXAMINER